

PSJ10 Exh 35

Message

From: Nancy Baran [/O=ONETEAM/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=NBARAN]
Sent: 8/18/2009 10:55:26 PM
To: John LaRocca [/O=ONETEAM/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=JLAROCCA]
CC: Michael Perfetto [/O=ONETEAM/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=MPERFETTO]; Doug Boothe [/O=ONETEAM/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=DBOOTHE]
Subject: FW: Suspicious Orders

John,

The quick answer to the first part of your question is that we do have a process in place to govern the ordering of controlled drugs. The longer answer is that I believe our process is not current and there is significant room for improvement. I have recommended that we bring in a few key players from different functional areas all of whom have shared ownership in the process. The main goal is to confirm that we are meeting our obligation as a manufacturer of these controlled drugs. This task is on our project list. I plan on leading the initiative and IT has committed to providing development support as needed.

The process as it stands today dates back to November of 2000 when the Suspicious Order Report was developed. As far as I can tell, there have been little or no changes to the report since that time. A brief explanation of how the report was intended to work is as follows -

An order appears on the suspicious order report if it meets the following criteria:

- If the amount ordered by the customer is 25% over the customer's rolling average ([see e-mail below for more details](#))
- The 25% threshold will increase to 40% for abuse type drugs.
- The suspicious order report is printed several times/day. There is a separate suspicious order report for SSL and SOD.
- The report is printed automatically at the time that the EDI orders are received. The report does not include manually entered orders.
- Customer Service reviews (eyeballs) the suspicious order report throughout the day (when a new report is created).
- Any order that looks unusual is investigated and any unusual items are cleared before the order is released.

Hamlin, Lisa

From: Hamlin, Lisa
Sent: Friday, November 03, 2000 12:05 PM
To: Levitt, Michael
Cc: Corridon, Pat; Reed, John
Subject: Suspicious Order Report

Suspicious Order Report:

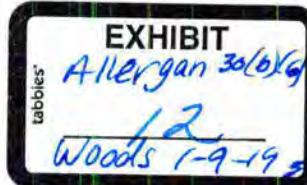
At the beginning of each month, the program looks back over last month's **invoices** by customer and item

All the quantities **ordered** and a count of the number of lines are totaled and saved.

The totals of each for the past 6 months (rolling) are added up and an average is computed by dividing the 6 month qty ord / 6 month line count.

This is your "customer item average".

New sales orders are considered suspicious if the qty ordered is more than 1.25 * the customer average (ie., more than 25% over average).



Examples:

if you order 1,000 once a month, your average is 1,000

if you order 10 times a month, 100 units each time, your average is 100.

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To answer the second part of your question –

We would never ship to unfamiliar customers. Our system is set up to prevent shipping a controlled product to a customer without a valid DEA license.....which is a document governed by the DEA who determines the customers eligibility. Our customer master database is updated monthly by means of a download of their eligibility data. Without a valid DEA license, an order will fail at point of entry. Our system (MFG PRO) will generate a failure report for any order rejected for DEA purposes/lack of current license in our system. Our 3rd party logistic provider (UPS-SCS) has a level of security equally as secure as our systems acting as a secondary checkpoint. This makes it virtually impossible to sell to a customer that is not authorized to distribute controlled products.

I hope that I have sufficiently answered your questions and apologize if I have provided more detail than you were looking for. If you have any further questions, don't hesitate to ask.

Nancy

Nancy Baran
Senior Manager, Customer Service



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From: John LaRocca
Sent: Friday, August 14, 2009 6:58 PM
To: Nancy Baran; Michael Perfetto
Cc: Doug Boothe
Subject: Suspicious Orders

Nancy, Mike – do we have a written procedure in place to govern the handling of orders for Class II drugs that are out of line with previous experience from customers, from unknown customers, or are for unprecedeted amounts? Also what is the procedure by which we get comfortable that our customers are registered and permitted to handle Class II's?

John LaRocca
Vice President/Chief Legal Officer



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